

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	
SAREPTA THERAPEUTICS, INC.,)	C.A. No. 21-1015 (JLH)
Defendant.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant and Counter-Plaintiff)	
)	
v.)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC., Plaintiff and Counter-)	
Defendants.)	

**NIPPON SHINYAKU CO. AND NS PHARMA, INC.'S
REPLY LETTER REGARDING REQUEST FOR LEAVE TO FILE
MOTION FOR SUMMARY JUDGMENT**

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Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: October 1, 2024

Dear Judge Hall:

The Court’s July 2, 2024 Order states: “A party that believes it is entitled to summary judgment based on an issue **affected by** the supplemental expert reports may file a three-page letter seeking leave to file summary judgment on October 2, 2024.”¹ D.I. 597 (emphasis added). Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, “NS”) followed that direction. *See* D.I. 604. Although it was not required to do so, NS also attached its proposed filing for the Court’s convenience—including a statement of undisputed facts with supporting citations to supplemental expert reports and supplemental expert depositions—so the Court could more readily evaluate the bases on which NS intends to move and so Sarepta had more time to prepare a response. *See id.*

Defendant/Counter-Defendant Sarepta Therapeutics, Inc. (“Sarepta”) does not deny that NS followed the Order; *i.e.*, NS filed a letter and relies on new facts from supplemental expert discovery. Instead, Sarepta reads a new requirement into the Order—that no exhibits are allowed—and accuses NS of violating that non-requirement. *See* D.I. 605. This strawman argument is no reason to deny NS’s request. Sarepta’s other objection, that NS violated the Local Rules by failing to meet and confer with Sarepta prior to filing its motion, is also meritless. L.R. 7.1.1 relates to “**nondispositive motions**” and further requires meeting and conferring “[u]nless otherwise ordered.” NS’s proposed motion is a **dispositive motion**, and this Court “otherwise ordered” by entering D.I. 597 without mention of a requirement for meeting and conferring.

Sarepta next argues that the motion “seeks to relitigate issues that were already considered and rejected by the Court” because “NS previously moved for summary judgment on written description and enablement grounds.” D.I. 605. While NS did move previously, its new proposed motion depends on new facts from supplemental expert discovery that could not have been raised before and confirm invalidity. *See* D.I. 604-4 (NS’s statement of undisputed facts, relying heavily on new facts from supplemental expert discovery). NS also presents new legal theories supported by these facts. *See, e.g.*, D.I. 604-3 at 11 (explaining how there are insufficient “blaze marks” to guide a POSA to the “hot spot” to satisfy written description); *id.* at 15 (explaining how claim 1 is directed to all levels of exon 53 skipping but the specification at best only enables “very faint skipping”). NS also relies on new cases, including *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1384 (Fed. Cir. 2012), that were absent from its previous brief. Therefore, that the Court previously denied NS’s prior motion is no reason for this Court to reject NS’s new motion.

Finally, Sarepta challenges the facts upon which NS relies, arguing there are genuine disputes. These are arguments that should be considered in ruling on the motion and not at the letter stage. Further, none of the facts that Sarepta disputes relate to NS’s enablement argument.

NS seeks to conserve judicial resources, streamline the trial in this matter, and have the Court resolve the purely legal invalidity issues raised in its motion for summary judgment. NS therefore respectfully requests the Court grant it leave to file its motion for summary judgment and resolve the motion prior to the scheduled December 2024 trial.

¹ NS interpreted this direction to mean by October 2, 2024. NS filed its letter several days early and immediately following the close of supplemental expert discovery.

Dated: October 1, 2024

Respectfully submitted,

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